UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ASGEIR SAEBO, CARL SKARIE, DARIA JEROME, and GUDMUNDER HAROLDSSON

Appeal No. 2005-0150
Application No. 09/271,024

HEARD: June 7, 2005

Before WILLIAM F. SMITH, ADAMS and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 5-8 and 13-17, which are all the claims pending in the application.[1]

Claims 5 and 13 are illustrative of the subject matter on appeal and are reproduced below:

5. A biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R1, R2, and R3 attached at the positions of the OH-

[1] While the examiner states (Answer, page 2), "[t]he statement of the status of the claims contained in the brief is correct," we note that appellants' Brief does not address the status of claim 12. For clarity, we note that appellants cancelled claim 12, along with claims 1-4 and 9-11 in the amendment (see page 1) received November 14, 2000.

groups of a glycerol backbone, and wherein R1, R2 and R3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R1, R2 and R3, wherein said percentages are peak area percentages as determined by gas chromatography.

13. A composition comprising a prepared food product containing a biologically active acylglycerol composition comprising a plurality of acylglycerol molecules wherein the acylglycerol molecules comprise substituents R1, R2, and R3 attached at the positions of the OH-groups of a glycerol backbone, and wherein R1, R2 and R3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least approximately 30% t10,c12 octadecadienoic acid, at least approximately 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R1, R2 and R3, wherein said percentages are peak area percentages as determined by gas chromatography.

The references relied upon by the examiner are:

Pariza et al. (Pariza)	5,017,614	May 21, 1991
Nilsen et al. (Nilsen)	5,885,594	Mar. 23, 1999
Cain et al. (Cain)	WO 97/18320	May 22, 1997

GROUNDS OF REJECTION

Claims 5-8 stand rejected under 35 U.S.C. 102(a) as anticipated by Cain.

Claims 13-17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Cain.

Claims 5-8 and 13-17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Nilsen in view of Cain and Pariza.

We reverse.

DISCUSSION

According to the examiner (Answer, page 3), the basis for each rejection is "fully set forth in prior office action, paper No. 26, mailed March 26, 2003." However, upon inspection of the Office Action mailed March 26, 2003 (see page 2), we find that instead of providing a statement of the rejection, the examiner refers to the "reasons set forth in the prior office action." It is in the Office Action mailed August 13, 2002 where we find a statement of each rejection on this record. We remind the examiner, as set forth in § 1208(A) of the Manual of Patent Examining Procedure

> Examiners may incorporate in the answer their statement of the grounds of rejection merely by reference to the final rejection (or a single other action on which it is based, MPEP § 706.07). Only those statements of grounds of rejection appearing in a single prior action may be incorporated by reference. An examiner's answer should not refer, either directly or indirectly, to more than one prior Office action. Statements of grounds of rejection appearing in actions other than the aforementioned single prior action should be quoted in the answer.

THE REJECTION UNDER 35 U.S.C. § 102:

According to the examiner (page 3, Office Action, mailed August 13, 2002),

> Cain teaches [example 6] an acyglycerol composition comprising mono-[,] di-[,] and tri-glyceride[s] wherein the fatty acid[s] are c9,t11 CLA[2] or t10, c12 CLA, wherein the total CLA in the composition is about ... [61.9%], of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer. No other CLA isomers are indicated, or suggested to be present in the composition.

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[2] According to Cain (page 1), CLA refers to compositions containing free conjugated linoleic acid. Cf. appellants' specification (page 9), "[a]s used herein, 'conjugated linoleic acid' or 'CLA' refers to any conjugated linoleic acid or octadecadienoic free fatty acid."

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). "Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Upon review of Cain we agree with the examiner that example 6 of Cain teaches a composition comprising "61.9% of conjugated linoleic acid (CLA) of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer." In addition, we agree with the examiner that Cain is silent regarding the presence of other CLA isomers that may be present in the composition. Thus, the composition taught by Cain appears, in the first instance, to meet all the limitations of appellants' claimed invention. Accordingly, we find that the examiner has established a sufficient evidentiary basis to shift the burden to appellants to demonstrate that Cain does not anticipate their claimed invention. In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) ("when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."). In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d 660, 664, 169 USPQ 563, 566 (CCPA 1971).

In response, appellants assert (Brief, page 5), Cain "does not anticipate [c]laim[s] 5-8 because the methods utilized by Cain et al. cannot produce the claimed CLA isomer profile (i.e., a CLA composition containing less than 1%

total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid isomers)." In support of this assertion, appellants direct our attention to the Saebo Declaration, which according to appellants "establishes that the compositions of Cain et al. necessarily include the 8,10 and 11,13 isomers of CLA." According to the Saebo Declaration (paragraph 4),

> In the repeat of Cain, the conjugation conditions were the same as those described in Example 6 of WO97/18320. The results of the conjugation reactions were analyzed by GC-MS. ... [T]his conjugation method resulted in a conjugated linoleic acid composition comprising approximately 3.49% c11,t13 CLA and 2.24% t9,t11 and t10,t12 CLA. The t8,c10 isomer co-elutes with the c9,t11 isomers, but almost always occurs in a one to one proportion to the c11,t13 isomer.

From this, appellants assert (Brief, page 8), "[a]pplicants followed the exact instructions of Cain and analyzed the product. The [a]pplicants did not fail to obtain CLA. Indeed, they obtained CLA with the isomers described by Cain et al. However, the fact remains that the CLA also contained other isomers that are not mentioned by Cain." According to appellants (Brief, bridging paragraph, pages 8-9), Cain's "silence concerning the presence of the isomers cannot be equated with the absence of the isomers. ... [Cain] does not specifically define CLA to include non-active CLA isomers." On this point the Saebo Declaration states (paragraph 5),

> [t]he [e]xaminer states ... that Cain teaches CLA compositions that are composed of 48.9% c9,t11 and 51.1% t10,c12 CLA, and that the analysis was carried out with gas chromatography and no other isomer of conjugated linoleic acid is detected. However, this does not mean that the other isomers were not present, as was found in my repeat of Cain. This discrepancy is explainable by the facts that 1) methods for the analysis of CLA compositions in 1996 were rather crude and 2)

> Cain may have simply chosen not to include non-active isomers when reporting their results.

In addition, appellants direct our attention to Sugano[3]. Brief, bridging paragraph, pages 10-11.[4] According to appellants (id.), Sugano "isomerized linoleic acid [under] conditions similar to those described by Cain...." However, as appellants explain (id.), in contrast to the results reported by Cain, Sugano's "resulting CLA preparation contained the following CLA isomers: 29.8% c9,t11/t9,c12; 1.3% c9,c11; 1.4%c10, c12; 18.6% t9,t11/t10,t12; 5.6% linoleic acid; and 13.7% other isomers." In view of the foregoing, appellants assert (Brief, page 11), "[i]n contrast to the simplified analysis presented in Cain et al., isomerization of CLA results in the production of many different isomers, not just the desired c9,t11 and t10,c12 isomers."

Appellants also direct out attention (Brief, page 11), to examples 1-4 of their specification in further support of their position that the methodology taught by Cain would have resulted in the production of CLA compositions that do not meet the limitations of their claimed invention. According to appellants (id., emphasis removed),

> [t]hese examples compare non-aqueous alkali isomerization under high or low temperatures and aqueous alkali isomerization under high or low temperatures. The important fact to note is that

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[3] Sugano et al. (Sugano), "Conjugated Linoleic Acid Modulates Tissue Levels of Chemical Mediators and Immunoglobulins in Rats," Lipids, Vol. 33, No. 5, pp. 521-527 (1998).

[4] Appellants also direct out attention to "Chapter 5 of the book Advances in Conjugated Linoleic Acid Research, Volume 2, J. Sebedio, W.W. Christie, and R. Adolf, Eds., AOCS Press, Champaign, IL, 2002...." See Brief, bridging sentence, pages 9-10. This reference, however, was published after appellants' March 17, 1999 filing date. Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. See In re Gunn, 537 F.2d 1123, 1128, 190 USPQ 402, 405 (CCPA 1976). Accordingly, we have not considered this reference.

> each reaction, even the low temperature non-aqueous alkali isomerization reaction (Example 1, Table 6), produced a distribution of the expected isomers, not just the c9,t11 and t10,c12 isomers.

From this appellants assert (id., emphasis removed), "the compositions of Cain necessarily contained levels [of] 8,10; 11,13; and trans,trans isomers that do not meet the[ir] claimed levels."

In response, the examiner appears to back away from his original finding (page 3, Office Action, mailed August 13, 2002) that "[n]o other CLA isomers are indicated, or suggested to be present in the composition" taught by Cain. In response to appellants' arguments, and contrary to his original inference, the examiner asserts (Answer, page 4), "nowhere in Cain states that 'conjugated linoleic acid' are exclusively for c9, t11; and t10, c12 isomers." Thus, the examiner appears to concede that the CLA compositions taught by Cain would be expected to contain additional CLA isomers other than the c9, t11; and t10, c12 isomers identified by Cain.

The examiner maintains, however, "there is no convincing evidence showing that Cain's composition has the amount of the particular isomers herein claimed." Apparently the examiner is referring to the requirement of appellants' claimed invention that the acylglycerol composition comprise "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R_1, R_2 and R_3 ...." While the examiner appreciates that the composition taught by Cain would contain CLA isomers other than t10,c12 and c9,t11 octadecadienoic acid, the examiner makes no

attempt to explain why the compositions taught by Cain would necessarily contain "less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R_1, R_2 and R_3 ..." as required by appellants' claimed invention. The only evidence on this record that addresses this point is appellants'. As discussed above, both the Saebo Declaration (using the same methodology as set forth in Cain), and the Sugano reference (using a similar methodology as set forth in Cain), resulted in a CLA composition that contained more than "about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid at positions R_1, R_2 and R_3 ...." In our opinion, the evidence of record weighs in favor of appellants, and rebuts the examiner's prima facie case of anticipation.

Accordingly, we reverse the rejection of claims 5-8 under 35 U.S.C. § 102(a) as anticipated by Cain.

THE REJECTIONS UNDER 35 U.S.C. § 103:

Cain:

According to the examiner (page 3, Office Action, mailed August 13, 2002), "Cain teaches an acylglycerol composition comprising mono-[,] di-[,] and tri-glyceride[s] wherein the fatty acids are c9,t11 CLA or t10, c12 CLA, no other CLA isomers are indicated, or suggested to be present in the composition. See, example[s] 6-10 at page[s] 16-22." The examiner finds that Cain characterize

> all the fatty acid[s] through gas chromatography and ... identified the CLA. For example, in example 6, ... [Cain] state[s] "[t]he fatty

> acid composition of the product, as determined by FAME GC, contained 63.8% CLA, of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer." See page 16, lines 17-21.

From this the examiner asserts (id.), "the rest of the fatty acids are not CLA, and the CLA is composed entirely of cis 9, trans 11[ ]isomer and trans 10, cis 12 isomer."

In addition, the examiner finds (Answer, bridging paragraph, pages 3-4) that Cain teaches the use of the acylglycerol composition "in various food products including ice cream, soup, and bakery products. See, particularly, examples 12-17 at page 24-35 and the claims." The examiner recognizes, however, that Cain does not teach "that each of the isomers must be 30% or more of the total CLA moieties for the particular food products." Answer, page 4. Nevertheless, the examiner asserts (id.),

> it would be obvious to employ such [a] CLA composition in the food product, since such [a] CLA composition [comprising 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer] has been expressly disclosed by Cain [for use in a food product]. See, ... example 6.

In response, appellants assert (Brief, page 12), "[a]s established above [with regard to the rejection under 35 U.S.C. 102(a)], the compositions of Cain necessarily contain levels [of] 8,10; 11,13; and trans,trans isomers that do not meet the claimed levels. Thus, Cain et al. does not render the claims obvious." Similarly, the examiner relies on his response to the anticipation rejection. See Answer, page 6.

Accordingly, for the reasons set forth above, we find that the evidence of record weighs in favor of appellants. Therefore, the rejection of claims 13-17 under 35 U.S.C. § 103 as being unpatentable over Cain is reversed.

Nilsen in view of Cain and Pariza:

According to the examiner (page 4, Office Action, mailed August 13, 2002), Nilsen "teach a composition comprising 90-100[]% of an acylglycerol compound wherein the fatty acid radical is a conjugated polyunsaturated fatty acid." In this regard, the examiner finds (id.), "[t]he preferred conjugated polyunsaturated fatty acid is conjugated linoleic acid which is defined as c9, t11-octadecadienoic acid and/or c10, t12-octadecadienoic acid." The examiner recognizes, however, that Nilsen does not teach "the employment of the combination of c9, t11-octadecadienoic acid and/or t10, c12-octadecadienoic acid in the acylglycerol, or the specific amounts of each of the two isomers...."

The examiner relies on Cain to make up for Nilsen's deficiency regarding the specific c9, t11, and t10, c12 isomers of octadecadienoic acid in the acylglycerol taught by Nilsen. According to the examiner (page 5, Office Action, mailed August 13, 2002), Cain "teach[es] that both c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid are considered the active isomers of CLA, and are known to be beneficial for animal health." In this regard, the examiner relies on Pariza (id.), "to show that [a] person of ordinary skill in the art possess the skill of preparing/or isolating the pure single isomer employed herein. See,

particularly, column 4, line 50, bridging column 8, lines 68, wherein, the separation, purification, and analysis of the isomers are discussed."

To make up for Nilsen's failure to teach an acylglycerol composition containing at least approximately 30% c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid, the examiner asserts (id.), "[t]he optimization of the ratio of the compounds is considered within the skill of the artisan."

Based on this evidence, the examiner finds (id.),

> it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed ... invention was made, to make the composition of Nilsen et al. with acyglycerol [sic] compounds wherein the fatty acid moiety is a mixture of about equal amounts of c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid and employ the composition in feed for animals.

In this regard, the examiner asserts (id.), Nilsen did "not use ... other isomers of conjugated linoleic acids.... Therefore[, Nilsen] meet[s] the limitation set forth in claim 5 that other isomers are present in amounts less than 1%...."

In response, appellants assert (Brief, page 13), Cain "does not teach compositions comprising less than 1% 8,10; 11,13; and trans-trans isomers or methods of obtaining such compositions." Regarding Nilsen, appellants assert (id., emphasis removed), like Cain, Nilsen "provides no such compositions or methods [nor does Nilsen] teach any method at all for conjugation, they merely list CLA in a long list of fatty acids that may be useful in their invention." In support of this assertion, appellants rely on paragraph 6 of the Saebo Declaration which states "[w]ith respect to the Nilsen reference, I note that it does not provide any method of producing conjugated linoleic acid having less

than 1% 8,10; 11,13; and trans-trans isomers." Regarding Pariza, appellants assert (Brief, bridging paragraph, pages 13-14), "does not teach preparation of CLA in amounts suitable for incorporation into acylglycerides. Indeed, the HPLC purified isomers are produced for use as chromatography standards. Importantly, because the isomers are produced for use as standards, Pariza does not teach or suggest combining the isomers to form a composition containing both t10,c12 and t9,c11 isomers are required by the [c]laims." See also Saebo Declaration, paragraph 7. Accordingly, appellants assert (Brief, page 14), Pariza "teaches away from a combination of isomers as required by the [c]laims."

In response, the examiner addresses each reference individually. Accordingly, we will address the examiner's discussion of each reference in turn.

Cain:

The examiner relies (Answer, page 8) on his response to the anticipation rejection to address appellants' assertions regarding Cain. Accordingly, for the reasons set forth above, we are not persuaded by the examiner's assertion.

Nilsen:

Regarding Nilsen, the examiner asserts (id.), "one of ordinary skill in the art would have been expected to be able to practice the invention claimed by Nielsen [sic], including making an acylglycerol compound wherein the Rs are conjugated linoleic acids (specifically defined as c9, t11; t10, c12 isomers), see the claims in Nielsen [sic] et al." We fail to see the relevance of the examiner's reference to the claims of Nilsen. Upon consideration of Nilsen's claimed

invention we find no specific reference to c9, t11; t10, c12 isomers of CLA. At best, Nilsen's claims relate to a genus of CLA isomers. In this regard, we note the examiner's reference (Answer, page 6, emphasis added), to column 4, lines 4-6 of Nilsen, for what the examiner believes to be Nilsen's disclosure of "[t]he preferred conjugated polyunsaturated fatty acid ... which is defined as c9, t11-octadecadienoic acid and/or c10, t12-octadecadienoic acid." Appellants' claimed invention is directed to, inter alia, an acylglycerol composition containing at least approximately 30% t10, c12 octadecadienoic acid, not c10, t12-octadecadienoic acid. The examiner identifies no section of Nilsen, and we find none, that would suggest appellants' specific acylglycerol composition. Further, the examiner offers to response to appellants' assertion that Nilsen provides no method through which to produce an acylglycerol composition as set forth in appellants' claimed invention. Accordingly, we are not persuaded by the examiner's assertions to the contrary.

Pariza:

In response to appellants' argument concerning Pariza, the examiner asserts (Answer, page 8), "[a]ppellants concede[] that Paris [sic] et al. does provide purified CLA isomers, but nevertheless argue that Pariza's disclosure is for producing standard samples for HPLC, and is not in a scale suitable for making acylglycerol herein claimed." To this the examiner asserts (id.), "there is no limitation as to the quantity of the composition in claims 5-8." On reflection, we are not persuaded by the examiner's assertions.

While appellants do not dispute that Pariza teaches methods of making t10, c12 and c9, t11 octadecadienoic acid, appellants assert (Brief, page 13), "Pariza does not teach preparation of CLA in amounts suitable for incorporation into acylglycerides. Indeed, the HPLC purified isomers are produced for use as chromatography standards." In response, the examiner does not dispute that amount of t10, c12 and c9, t11 octadecadienoic acid produced in the method of Pariza would not be sufficient to produce appellants' claimed acylglycerol composition. Instead, the examiner concludes (Answer, page 8), "preparative HPLC would be obvious to one of ordinary skill in the art with similar condition[s]." Apparently, it is the examiner's position that a person of ordinary skill in the art would have found it obvious to scale-up the method taught by Pariza to produce a sufficient amount of t10, c12 and c9, t11 octadecadienoic acid to incorporate into acylglycerol molecules. The evidence of record, however, does not support the examiner's assertion. Further, the examiner fails to provide any evidence that the method taught by Pariza could be effectively scaled-up to produce the acylglycerol molecules required by appellants' claimed invention. In the absence of a reasonable expectation of success one is left with only an "obvious to try" situation which is not the standard of obviousness under 35 U.S.C. § 103. See In re O'Farrell, 858 F.2d 894, 904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

In order to establish a prima facie case of obviousness, there must be more than the demonstrated existence of all of the components of the claimed subject matter. There must be some reason, suggestion, or motivation found in

the prior art whereby a person of ordinary skill in the field of the invention would make the substitutions required. That knowledge cannot come from the applicants' disclosure of the invention itself. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). On the record before us, we find no reasonable suggestion for combining the teachings of the references relied upon by the examiner in a manner which would have reasonably led one of ordinary skill in this art to arrive at the claimed invention. The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In our opinion, the examiner has failed to provide the evidence necessary to support a prima facie case of obviousness.

Accordingly, we reverse the rejection of claims 5-8 and 13-17 under 35 U.S.C. § 103 as being unpatentable over Nilsen in view of Cain and Pariza.

REVERSED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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